

AMENDMENTS TO THE SPECIFICATION

In the Title:

APPARATUS ~~USABLE IN HAEMOFILTRATION~~ AND METHOD FOR THE TREATMENT OF BLOOD

Please replace the paragraph beginning at page 1, line 4, with the following rewritten paragraph:

The present invention relates to an apparatus ~~usable~~ and a method for the treatment of blood, usable, in particular, in CRRT (Continuous Renal Replacement Therapy) treatment.

Please replace the paragraph beginning at page 2, line 20, with the following rewritten paragraph:

Another drawback of known CRRT systems is the compulsory use of a pump for the ultrafiltrate, which is less tolerable by chronic, haemodynamically unstable patients whose refill capacity is always unknown. Furthermore, the known CRRT machine are relatively complex and comprising a lot of elements.

Please replace the paragraph beginning at page 2, line 27, with the following rewritten paragraph:

According to the present invention, there is provided ~~a CRRT apparatus as claimed in Claim 1 and the dependent Claims:~~ an apparatus and a method for the treatment of blood as more particularly defined in the enclosed claims.

Thus, an apparatus according to the invention is for CRRT therapy of the type performable using a haemofiltration machine and which comprises: connecting means from and to respective blood vessels of a patient; blood processing means comprising a pump; means for adding drugs or other therapeutic substances to the blood being treated; means for feeding refill liquid into the blood; blood filtration means, cascade-connected to one another by relative conduits, said conduits and said connecting means defining a blood path; wherein said apparatus

comprises an oxygenating device comprising an oxygenating membrane and it is located upstream from said blood filtration means and downstream from said blood processing means so that the said oxygenating membrane of the oxygenating device operates without the intake pressure along the portion upstream from the blood pump; and wherein said pump pumps the blood downstream from the connecting means to the oxygenating device at a flow rate of 280-300 ml/min.

A method according to the invention is a method for the treatment of the blood in a Continuous Renal Replacement Therapy, using a machine which comprises: connecting means from and to respective blood vessels of a patient; blood processing means comprising a pump; means for adding drugs or other therapeutic substances to the blood being treated; means for feeding refill liquid into the blood; blood filtration means, cascade-connected to one another by relative conduits, said conduits and said connecting means defining a blood path; a method wherein the blood to be treated passes through an oxygenating device which comprises an oxygenating membrane and is located upstream from said blood filtration means and downstream from said blood processing means, so that the blood is treated by said oxygenating membrane without the intake pressure along the portion upstream from the blood pump; and wherein the blood is pumped downstream from the connecting means to the oxygenating device at a flow rate of about 280-300 ml/min.

The advantages of the apparatus and of the method according to the present invention substantially lie in greatly improving "~~decapneisation~~"decapneisation", i.e. in greatly reducing the CO₂ values of the blood. By way of example, reducing FiO₂ from 100 to 70% has been found to increase O₂ saturation of the patient from 92 to 100%. This is extremely important, in that the poor capacity of the lung to exchange O₂ constitutes a serious complication in many patients. Another advantage lies in the principle of the present invention being applicable to existing machines, which can be altered to achieve more complete, more effective performance. Moreover, the characteristics of an apparatus in accordance with the invention remain unchanged with very little maintenance.

Please replace the paragraph beginning at page 4, line 11, with the following rewritten paragraph:

Pump 3 pumps the blood downstream (in the direction shown by the arrows) to a connecting member 4, after first adding heparin by means of a conduit 50 connected to conduit 91 and to a heparin tank (syringe) 5. A conduit 60 is connected to the input of connecting member 4 to supply, by means of a pump 61, a refill liquid or infusion contained in a tank 6 and heated by heating means 62.

In is important that the apparatus has only one pump 3 because this feature allows a better treatment of the blood, with a reduced hemolysis.

A gauge 40 is provided at connecting member 4 to measure the pressure at that point along the path.

Downstream from connecting member 4, conduit portion 92 is connected to an oxygenating device 7 or "~~decapneisator~~"decapneisator", which may be a Jostra Polystan mycro or Jostra Safe mycro neonatal type, and which is connected by a conduit 77 to an oxygen source (i.e. a tank 78 or an oxygen supply system), and is fitted inside with an oxygenating membrane 71. Oxygenating device 7 provides for supplying oxygen to eliminate CO₂ from the blood; for which purpose, CO₂ is eliminated through an outlet 70 of device 7 and sent to measuring means not shown.

Downstream from "~~decapneisator~~"decapneisator" 7, conduit portion 93 is connected to a blood filter or haemofilter 8 having an output connected to a conduit 80 for discharging ultrafiltrate into a collecting tank 81. Conduit 80 is fitted with control means 82, which may be defined, for example, by a detector for detecting blood loss in the ultrafiltrate, and which acts directly on conduit 80.

Please replace the paragraph beginning at page 4, line 26, with the following rewritten paragraph:

In other words, an apparatus in accordance with the present invention comprises a CRRT machine, and an oxygenating device or "~~decapneisator~~"decapneisator". By way of example, the CRRT machine may be an Equasmart Medica equipped with appropriate connecting tubes, catheters, connections, etc.

Please replace the paragraph beginning at page 7, line 2, with the following rewritten paragraph:

Again at therapy level, a weight loss (i.e. the quantity of liquid to be drained) may be set as required in each specific case, i.e. as prescribed by the physician. An anticoagulant infusion in line with standard CRRT protocols will therefore be provided, with a blood flow rate (QB) of over 300 ml/min, and an oxygen flow rate (QO₂) higher than QB. It is important to continuously monitor both coagulation time, which must be kept constantly at one and a half times normal, and oxygen saturation, haematocrit, blood volume values, etc. For this purpose, a CRITE-LINE or similar apparatus may be used.

In conclusion, the present invention relates to a procedure aimed to the continuous removal of the CO₂ from the blood. This procedure employs a CRRT system, and it is easily applicable in any Intensive Care Unit.

Up to day, various pathologies have been found that could benefit of the decapneization treatment; mainly in RDS (Respiratory Distress Syndrome) where it allows the forced ventilation to be kept in hyper-protective condition (where air pressure, O₂ concentration and breathing frequency are within safety levels) where, besides the advantages of the reduced risk of induced chronic distress to the patient's lungs, there is a reduced production of pro-inflammatory substances from the lungs, greatly increasing the possibility of positive evolution of the case. Other applications are in BPCO (Chronic Bronchitis), in Post Operatory lungs and trachea patients, for brain lesion and, in general, to avoid Pulmonary Fibrosis in all the cases of prolonged forced ventilation.

The method consists in the use of a small oxygenator (also called decapneizator) along in an extracorporeal circuit in pre-dilution with an haemo-concentrator immediately after the oxygenator itself. This allows a low blood concentration in the decapneizator thus reducing the needs for Heparin. The pressure induced by the flow resistance of the haemo-concentrator prevents any air passage in the blood flow, furthermore the ultra filtrated fluid from the haemo-concentrator contains CO₂ that is easily removed by the passage in the decapneizator device.